

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	)
	)
Anderson et al.	)
	)
Reissue of U.S. Patent No. 5,399,346	)
Issued March 21, 1995	)
	)
Assigned to: The United States of	)
America as represented by the	)
Department of Health and Human	)
Services	)
	)
For: Gene Therapy	)

**REISSUE APPLICATION DECLARATION AND POWER OF ATTORNEY**

1. The contents of the above-identified specification, including the claims has been reviewed by the assignee.
2. The assignee hereby acknowledges the duty to disclose information that is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.
3. The assignee makes this declaration in support of a reissue of the above-identified U.S. patent, which has been the subject of Interference Nos: 103,708, 104,710, 104,711, 104,712, 104,713, 104,714, and 104,715.
4. The assignee believes the patent to be partly invalid by erroneously claiming without deceptive intent more than the patentees had the right to claim.
5. The patent is partly invalid because original claims 1, 2-6, 8-11, 13 and 14 are too broad. Specifically, claim 1, and dependent claims 2-6, 8-11, 13 and 14, are too broad because claim 1 recites "a therapeutic protein."
6. In view of the above, claims 1-14 have been canceled and claims 15-26 have been added. Claims 15-26 are no broader than originally issued claim 1. Claims 15-26 serve to point

out more particularly and claim more distinctly the subject matter of the present invention.

Claims 15-26 are supported by the patent specification at, for example, column 2, line 3, through column 3, line 6, column 4, lines 21-44, and column 5, lines 14-26.

7. Also, claims 27-29 have been added. Claims 27-29 are no broader than originally issued claim 1. Claim 27 corresponds substantially to claim 7 of the originally issued patent, claim 28 corresponds, in part, to claim 8 of the originally issued patent, and claim 29 corresponds substantially to claim 9 of the originally issued patent.

8. The error in the patent, namely the inadvertent claiming of the invention more broadly than the patentees had a right to claim the invention is the result of error, without deceptive intent, on the part of the patentees. The error arose at the time that the patent application was prosecuted as a result of the failure to appreciate the impact on patentability of two prior art references, namely, Anderson et al., "*The ADA Human Gene Therapy Clinical Protocol*," (submitted to the Department of Health & Human Services on July 6, 1990), Human Gene Therapy, 1: 331-332 (1990) (hereinafter "the ADA Protocol") and Rosenberg et al., "*Gene therapy of patients with advanced cancer using tumor infiltrating lymphocytes transduced with the gene coding for tumor necrosis factor*" (submitted to the Department of Health & Human Services on July 6, 1990) (hereinafter "the TNF Protocol").

9. The error was discovered after issuance of the patent, as a result of an interference proceeding involving the patent (specifically, Interference No. 104,712). In that interference proceeding, the Board of Patent Appeals and Interferences determined that (i) originally issued claims 1-5, 8, and 9 of U.S. Patent No. 5,399,346 are unpatentable as anticipated by the ADA Protocol and (ii) that originally issued claims 1-6, 8-11, 13, and 14 are unpatentable as anticipated by the TNF Protocol.

10. Accordingly, the process claims of the instant reissue application have been amended in view of the disclosure of the ADA Protocol and in view of the disclosure of the TNF Protocol.

11. The assignee hereby appoints the National Institutes of Health, Office of Technology Transfer, 6011 Executive Blvd., Ste. 325, Rockville, Maryland 20852-3804, Telephone

In re Application of Anderson et al.  
Reissue Application for U.S. Patent No. 5,399,346

(301) 496-7056, as Principal Attorneys and to prosecute this application and transact all business in the U.S. Patent and Trademark Office connected therewith: Customer Number 05318.

05318

12. Please recognize Leydig, Voit & Mayer, Ltd. as Associate Attorneys in this case.  
Customer Number 23460.

23460

13. I further direct that correspondence concerning this application be directed to  
Leydig, Voit & Mayer, Ltd.: Customer Number 23460.

23460

14. I declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

The Government of the United States of America,  
as delegated to

By: \_\_\_\_\_

James C. Haight (#25,588)  
Senior Patent Attorney  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard, Suite 325  
Rockville, MD 20852

Dated: \_\_\_\_\_

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**CONSENT OF ASSIGNEE**

Mail Stop Reissue  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

1. The Government of the United States of America, as represented by the Secretary, Department of Health and Human Services, is owner of the entire right, title, and interest in this case, as evidenced by the assignment attached hereto. The National Institutes of Health Office of Technology Transfer has been duly delegated responsibility for such patent matters under the authority of DHHS Secretary Louis W. Sullivan's May 21, 1991, memorandum published in the Friday, June 7, 1991, Federal Register Notices at Vol. 56, pages 26418 - 26419.

2. The above assignment has been reviewed by the undersigned, who certifies that, to the best of his knowledge and belief, title is in the assignee as stated herein.

3. The United States of America as represented by the Department of Health and Human Services hereby consents to the reissue application identified above.

Respectfully submitted,

The Government of the United States of America,  
as delegated to

By: \_\_\_\_\_  
James C. Haight (#25,588)  
Senior Patent Attorney  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard, Suite 325  
Rockville, MD 20852

Dated: \_\_\_\_\_

## A S S I G N M E N T

WHEREAS, the undersigned, to wit:

- 1) W. FRENCH ANDERSON
- 2) R. MICHAEL BLAESE
- 3) STEVEN A. ROSENBERG
- 4) \_\_\_\_\_

residing at:

- 1) 6820 Melody Lane, Bethesda, MD 20817
- 2) 1986 Lancashire Drive, Rockville, MD 20854
- 3) 9015 Honeybee Lane, Bethesda, MD 20834
- 4) \_\_\_\_\_

(hereinafter collectively ASSIGNOR), has/have made an invention known as Docket 26388DO203 and entitled: GENE THERAPY

for which an application for Letters Patent of the United States [ ] was executed even date herewith and is about to be filed in the United States Patent and Trademark Office;

[X] was filed on June 14, 1989, Serial No. 0 / \_\_\_\_\_;

WHEREAS, the conditions under which said invention was made are such as to entitle the Government of the United States of America under Paragraph 1(a) of Executive Order 10096, to the entire right, title, and interest therein, including foreign rights; and

WHEREAS, as to foreign rights, it is the policy of the Government of the United States of America to obtain and option to exercise such rights;

NOW THEREFORE, to all whom it may concern, be it known that for and in consideration of Ten Dollars (\$10.00) and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, ASSIGNOR does hereby sell, assign, and transfer unto THE GOVERNMENT OF THE UNITED STATES OF AMERICA (AS REPRESENTED BY THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES) and his successors (hereinafter THE GOVERNMENT), the entire right, title, and interest throughout the United States of America, its territories and dependencies, in and to the aforesaid invention described in the aforesaid application for Letters Patent of the United States, and all Letters Patent issuing thereon and any continuations, divisions and reissues or extensions thereof;

AND, ASSIGNOR does her by authorize and request the Commissioner of Patents to issue said Letters Patent to THE GOVERNMENT as assignee of the entire right, title, and interest in and to the same throughout the United States of America, its territories and dependencies, for the sole use for the full term or terms for which said Letters Patent and any continuations, divisions, and reissues or extensions thereof are, or may be, granted as fully and entirely as the same would have been held by ASSIGNOR, had this assignment not been made;

AND, ASSIGNOR does hereby grant unto THE GOVERNMENT, the option to take all of the right, title, and interest in said invention and all applications for Letters Patent thereon in all countries foreign to the United States in which THE GOVERNMENT elects to file applications for Letters Patent, including the right to file such applications under the provisions of the International Convention claiming priority in the aforesaid United States application, without payment to me of any further consideration, provided, however, that this grant of an option to take foreign rights in ASSIGNOR'S invention, or applications for Letters Patent thereon, shall have force and effect only as to those foreign countries in which THE GOVERNMENT notifies me of its election to file foreign patents within six months of the filing date of any applications for United States Letters Patent covering the invention, and that all foreign rights not exercised under the option are left to ASSIGNOR'S subject to a nonexclusive, irrevocable, royalty-free license to THE GOVERNMENT in any patent which may issue on said invention in any foreign country, including the power to sublicense for use in behalf of THE GOVERNMENT and/or in furtherance of the foreign policies of THE GOVERNMENT;

AND, ASSIGNOR hereby warrant that there are no outstanding assignments, grants, liens, encumbrances, or agreements either written, oral, or implied with respect to the aforesaid application for Letters Patent which will impair, diminish, limit or abridge the interest herein conveyed at the time of the execution of this instrument by ASSIGNOR;

AND, ASSIGNOR hereby agree to execute any and all applications for Letters Patent, and to furnish all data and documents and to execute any papers which may be necessary for the preparation of filing of such domestic applications or for THE GOVERNMENT to exercise its option granted hereunder, including communicating to THE GOVERNMENT, its representatives or agents, any facts relating to said invention, including evidence for interference purposes, or for other proceedings, whenever requested, to testify in any interference or other proceedings, whenever requested, and to execute and deliver on request all

lawful papers required to make any of the foregoing provisions effective, and likewise make these provisions binding upon my heirs, legal representatives, administrators and assigns, except that it shall be understood that I shall not be subject to any out-of-pocket expense relative to any such action.

Executed on the date(s) below indicates.

<u>Signature</u>	<u>Date Signed</u>	<u>Witness</u>
1) <u>W. French Anderson</u> Name: W. FRENCH ANDERSON	<u>7/27/89</u>	<u>Elizabeth Lusso</u>
2) <u>R. Michael Blaese</u> Name: R. MICHAEL BLAESE	<u>7/27/89</u>	<u>W. French Anderson</u>
3) <u>Steven A. Rosenberg</u> Name: STEVEN A. ROSENBERG	<u>7/27/89</u>	<u>W. French Anderson</u>
4) _____ Name: _____	_____	_____